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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,446	03/04/2002	Clara L. Garcia-Rodenas	112843-027	4113

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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/03/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/936,446

Applicant(s)
Garcia-Rodenas et al.

Examiner
Randall Winston

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 7, 12, and 19 are rendered vague and indefinite for the phrase “and being in the form of.” One of ordinary skill in the art would not know (of what? i.e. the dietary protein hydrolysate) as “being in the form of.”

Claim 1, 7, 13, and 19 recite the term “in the form of a mixture of different size peptides and free amino acids.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning “in the form of a mixture of different size peptides and free amino acids.” There is no definition of “in the form of a mixture of different size peptides and free amino acids” in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention.

Claim 1 recites the term “intact proteins comprising bioactive proteins.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning “intact proteins comprising bioactive proteins.” There is no definition of “intact protein

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comprising bioactive proteins” in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention.

Claim 7 recites the term “intact proteins that are at least partially in the form of bioactive peptides.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning “intact proteins that are at least partially in the form of bioactive peptides.” There is no definition of “intact proteins that are at least partially in the form of bioactive peptides” in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention.

Claim 13 and 19 recites the term “intact proteins that are at least partly in the form of bioactive peptides.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning “intact proteins that are at least partly in the form of bioactive peptides” There is no definition of “intact proteins that are at least partly in the form of bioactive peptides” in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. (US 4,977,137).

Applicant claims a nutritional enteral composition and/or method of making and/or of use comprising of a mixture of dietary protein hydrolysates wherein the mixture of the dietary protein hydrolysate is in the form of a mixture of different size peptides and free amino acids (?) and intact proteins comprising and/or at least partially and/or at least partly in the form of bioactive peptides(?) wherein the composition also includes other active ingredients such as fats, carbohydrates, lipids, minerals and vitamins whereas the composition provides nutritions and/or promotes the growth and maturation of non-mature gastrointestinal tracts of young mammals.

Nichols et al. teach (see, e.g., claims 1-27) a dietary ingredient to a formula (i.e hydrolysed casein formula (see, e.g., col.11 lines 54- column 12 lines 23) comprising of milk lactoferrin (i.e. intact proteins) wherein the composition also includes the bioactive peptides of epidermal growth factors (see, e.g. column 2 lines 53-56 also see, US 5183805, title) and other active ingredients such as fats, carbohydrates, lipids, minerals and vitamins (see, e.g. entire document)to promote growth of the gastrointestinal tract of human infants and newborn nonhuman animals. Nichols et al. do not expressly teach active ingredients ranges/ratios as claimed. However, one of ordinary skill in the art would have been motivated to modify Nichols

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et al. to include the adjustment of other conventional working conditions such as (e.g. active ingredients ranges/ratios), particularly since the reference clearly indicates that the various proportions and amounts of the claimed composition are result effective variables and, thus, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by the reference. Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

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CHRISTOPHER R. TATE
PRIMARY EXAMINER